

EXHIBIT D

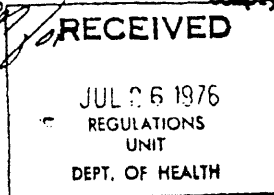
R-98-76
Ron Wetherall
9/500

Richard Ochener
 Legal Affairs and Regulation 8/1216

July 22, 1976

Preliminary Legal
 Review of Proposed Title 22
 Regulation Amendments to
 Comply with MAC/EAC

Original Signed by *CAP*
 Jay A. Gould, Chief
 Medi-Cal Benefits Section
 5-0380



As you know, we are working toward an August 26, 1976 implementation deadline for the subject regulations. We appreciate your willingness to make a preliminary review of this package as soon as possible. The proposed regulation changes (Attachment No. 1) are to bring the Medi-Cal Drug Program into compliance with the provisions of 45 CFR, Chapter 11, Part 250, Section 250.30 (b) (2) as specified in the Federal Register, 8/15/75, page 34519 (see Attachment No. 2).

Provision (ii) of this federal regulation, the Maximum Allowable Cost (MAC), is, in effect, the same type of program as our MAIC program. At such time as we receive the list of affected generic drug types and respective price limits from the U.S. Department of Health, Education, and Welfare, they will be integrated into Section 51513.3 (b) of our MAIC regulation. Our plan to meet provision (iii), Estimated Acquisition Cost (EAC), is described in Attachment No. 3. Relevant State authority to implement these necessary Title 22 amendments to comply with the federal provisions include California W & I Code, Sections 14053, 14105, 14124.5 and 14105.3.

A. Intent of the Proposed Title 22 Amendments Relevant to 45 CFR, Section 250.30 (b) (2), Provision (ii), the Federal MAC.

The federal MAC generic drug types and respective price limits will be listed in 51513.3 (b) and they will be identified to distinguish them from our MAICs. HEW has already established quality equivalence and product availability assurance for the affected generic drug types.

In this regard we wish to eliminate the necessity of duplicating this data, already established by HEW, because of our MAIC procedure requirements (51513.2). Also, in accord with the provision (ii) regarding the price limit waiver for MAC drugs, we wish to allow for payment of a more costly brand product, when medically necessary, for our California MAIC generic drug types.

The necessary regulation amendments to implement provision (ii), as shown in Attachment 1, include 51513 (a)(11), (13) and 51513.2. This intent of each amendment is as follows:

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Amendment to 51513 (a) (11)

Incorporates the federal MAC generic drug types into our MAIC drug type format (list of affected generic drug types and respective price limits not yet received from HEW).

Amendment to 51513 (a) (13)

Allows for waiver, via prior authorization, of a federal MAC or California MAIC price limit so that a more costly brand, when necessary, will be covered.

Amendment to 51513.2

Excludes duplication, via California MAIC administrative procedure, of establishing quality equivalence and product availability for federal MAC drugs.

B. Intent of the Proposed Title 22 Amendments Relevant to 45 CFR, Section 250.30 (b) (2), Provision (iii), the Federal EAC.

To comply with the "most frequently purchased package size" part of this provision, we will base unit price for certain drugs on package sizes larger than 100s. We will use federal data as our evidentiary base. However, in the future, we will want to expand this list to cover other drugs (including those which have an MAIC). In these cases we will want to establish our own most frequently purchased package size evidentiary base on a survey of a reasonable number of pharmacy providers and/or drug wholesalers and/or pharmaceutical companies.

To comply with the "closest estimate of the price generally and currently paid" part of provision (iii), we wish to be able to establish a criteria by which we can select a manufacturer for whose products we will pay the direct purchase price (which is usually 10 to 20 percent below the AMP). We would like to be able to establish this criteria by the general authority given the Director via proposed amendment 51513 (a) (9).

The criteria we have established, pursuant to policy interpretation of 51513 (a) (9), for selecting the manufacturer for whose products we will pay the Direct Price are:

1. Products account for approximately \$1 million/year or more Medi-Cal purchase, and/or;
2. Products are generally purchased and/or available to all Medi-Cal providers at a direct order discount, and/or;
3. Minimum direct order purchase terms for the products are reasonable and available to all Medi-Cal providers with good credit standing (i.e., \$75 or less minimum purchase requirement).

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For such manufacturers' products, we wish to pay the current direct price as listed in the Drug Topics Red Book, the American Druggist Blue Book, or the supplier's catalogue, and their respective supplements.

1. The necessary regulation amendments (as shown in Attachment 1) for the unit price based on the most frequently purchased package size specification of provision (iii) include Sections 51513 (a) (10), (d), 59999 (b) and 51513.2 (f). The intent of each amendment is as follows:

Amendment to 51513 (a) (10)

Extends standard package size definition to include package sizes larger than 100s, pints or pounds, so that unit price can be based on larger package sizes when it is determined that the larger package size is the most frequently purchased.

Amendment 51513 (d)

Specifies unit price payment on the most frequently purchased package size as determined pursuant to 51513 (a) (10).

Amendment to 59999 (b)

The generic drug type codes for which unit price is based and paid for on the basis of package sizes larger than 100s, pints, or pounds pursuant to 51513 (a) (10) and (d), are identified and cross referenced to Section 51513 (a) (10) and (d) for explanation.

Amendment to 51513.2 (f)

Allows establishment of MAIC unit price on the basis of most frequently purchased package size pursuant to Sections 51513 (a) (10) and payment pursuant to 51513 (d).

2. The regulation changes (shown in Attachment 1) are necessary to implement payment of the State's closest estimate of the price generally and currently paid for the products of a manufacturer whose products account for a million dollars per year or more Medi-Cal purchases; and/or whose products are generally purchased and/or available to Medi-Cal providers on a direct order basis; and/or whose minimum direct order terms are available and reasonable to all Medi-Cal providers. The changes include amendments to Sections 51513 (a) (9), (12); 51513 (e); 51513.2 (f); 59999 (e). The intent of each amendment is as follows:

Amendment to 51513 (a) (9)

Defines Direct Price and allows sufficient flexibility for the criteria by which manufacturers will be selected (to be established by policy determination rather than being locked into regulatory criteria).

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Amendment to 51513 (a) (12)

Incorporates Direct Price into Title 22 definition of product cost and quarterly price update provision.

Amendment 51513 (e)

Establishes payment for Rx ingredient cost on the basis of direct price, for all products of certain manufacturers identified in 59999 (e), pursuant to 51513 (a) (9) and (12).

Amendment to 51513.2 (f)

Allows MAIC to be established at the Direct Price if product is that of a manufacturer selected by the Director pursuant to 51513 (a) (9) and so identified in 51513 (e).

Amendment to 59999 (e)

Identifies pharmaceutical companies (manufacturers) for which reimbursement of their products will be based on the direct purchase price. Identified company is asterisked and cross referenced to Section 51513 (a) (9) and (e).

If you have any questions, please call Milt Kuechnereit of my staff at 5-0380.

Attachments
MK:rm

bcc: Lee Helsel
Deputy Director
Medi-Cal Division 8/1627
Ron Wetherall 9/500 ✓

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